IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:			
Richard A. Pittner, *et al.*			
Appln. No.:	10/016,969	Art Unit:	1646
Filed:	14 December 2001	Examiner:	Ruixiang Li
For:	PEPTIDE YY AND PEPTIDE YY AGONISTS FOR TREATMENT OF METABOLIC DISORDERS	Atty. Docket:	0401-UTL-0
		Confirm. No.:	7314

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Sir:

In response to the Final Office action dated July 26, 2006, Applicants respectfully submit the following Pre-Appeal Brief Request for Review in connection with the above-identified application.

Remarks begin on page 2 of this response.

REMARKS

Claims 33, 43-47, 51 and 54-74 are under consideration. No claim is allowed. In response to the Examiner's objection to claim 74 based on minor informalities, Applicant requests that this claim be canceled.

Specification

Applicants request confirmation that the Amendment to the first paragraph in the section titled "DETAILED DESCRIPTION OF THE INVENTION" on page 9 of the Specification, as requested in the response filed 17 May 2006, has been made.

Rejection Under 35 U.S.C. § 112, 1st paragraph, Enablement

Claims 33, 43-46, 51 and 54-74 were rejected under 35 U.S.C. § 112, 1st paragraph as allegedly lacking enablement. The Examiner alleges that the specification, while being enabling for PYY and PYY(3-36), "does not reasonably provide enablement for methods of administering a genus of PYY agonist analogs." In rebuttal to Applicant's citation of teachings of PYY agonists in the art, which were incorporated by reference into the specification as filed, the Examiner states that these "references do not teach the PYY agonist analogs in the context of reducing nutrient availability, food intake or body weight and do not teach how to identify a PYY agonist analog recited in the instant claims." (Pages 4-6 of Final Office Action mailed 26 July 2006). Applicant traverses this rejection for reasons of record as well as those discussed herein.

Firstly, Applicant agrees that the PYY agonists known in the art and incorporated by reference were not taught in the context of reducing nutrient availability, food intake or body weight – this would constitute anticipation of the invention under 35 U.S.C. § 102.

Secondly, the Examiner's rebuttal selectively addresses the known PYY agonists PP, NPY, NPY[3-36] and Ac-PYY[22-36] which were shown by applicants to not be active in the methods of the instant invention. However, other PYY agonists, such as PYY(4-36), PYY(6-36), PYY(10-36), PYY(13-36) and NPY(13-36) and were known in the art to activate Y receptors and were explicitly set forth on page 11 of Applicant's amendment mailed on 17 May 2006. Additionally, methods of making the claimed PYY agonists are provided (see page 12, lines 11-29 of the instant specification, as well as page 12 of Applicant's amendment mailed on 17 May 2006). Furthermore, Applicant amended the claims to include structural and functional definitions of the claimed genus of PYY

agonist analogs, such that the genus is further narrowed to a subset of PYY agonist analogs that do not comprise YP in the first two consecutive N-terminal amino acids, and which elicit a pharmacological effect at a subset of Y receptors. As argued continually throughout the prosecution history, Applicant's specification clearly sets forth means of determining whether a PYY agonist in this genus elicits one of the claimed pharmacological responses (i.e., reduction of food intake, appetite, nutrient availability, caloric efficiency, or body weight gain).

Because methods of making, identifying and using the claimed PYY agonists are provided, the invention is enabled. Applicants request reconsideration and withdrawal of this rejection.

Rejection Under 35 U.S.C. § 112, 1st paragraph, Written Description

Claims 33, 43-46, 51 and 54-74 were rejected under 35 U.S.C. § 112, 1st paragraph as allegedly lacking written description. The Examiner simply asserts that "(t)he limitation of 'PYY agonist analog is a peptide which does not comprise YP as its first two consecutive N-terminal amino acids' does not provide a structural feature of the recited PYY agonist analogs because it merely excludes PY from the amino acid sequence... but does not indicate what structure the PYY agonist analogs have." The Examiner further asserts that Applicant's amendment "'wherein the PYY agonist analog elicits a pharmacological effect at a Y2, Y5 or Y7 receptor greater than that of PYY[1-36] at a Y1 receptor' does not provide a definitive functional limitation for the PYY agonist analogs because it involves two varying factors..." (Page 7 of Final Office Action mailed 26 July 2006). Applicant traverses this rejection for reasons of record as well as those discussed herein.

As to the Examiner's first assertion, Applicant respectfully submits that, in the current view of the courts, negative limitations are allowable (See MPEP § 2173.05(i)). Page 6, lines 8-11 of the specification as filed recites "truncated PYY molecules having less than 36 amino acids, and substituted PYY molecules having one or more different amino acids, or any combination of the above." As to the Examiner's second assertion, methods of assessing the pharmacological effects of PYY agonists are provided, including Example 1, for example, in which the pharmacological effects of PYY(3-36) and PYY[1-36] are compared. It is not understood how the need to assess "two varying factors" makes this functional limitation lacking in written description.

With regard to the assertion that new claim 73 reciting "wherein the pharmacological effect at the Y1 receptor is an increase in blood pressure" introduces new matter and that there is "no sufficient support for the limitation at page 21 (lines 10-12), Applicants disagree. The specification

clearly cites measurement of blood pressure, and it was known in the art at the time of filing that the Y1 receptor mediates vasoconstriction and blood pressure increases (See page 10, col. 1 and page 14, col. 2 of the Gehlert reference).

Thus, the invention provides sufficient written description of the invention.

Rejection Under 35 U.S.C. § 112, 2nd paragraph, Indefiniteness

Claims 33, 43-46, 51, 54-72 and 74 were rejected under 35 U.S.C. § 112, 2nd paragraph as allegedly being indefinite. Applicant traverses this rejection for reasons of record as well as those discussed herein.

The Examiner states that these claims "are indefinite because they recite a limitation 'wherein the PYY agonist analog elicits a pharmacological effect at a Y2, Y5 or Y7 receptor greater than that of PYY[1-36] at a Y1 receptor'. First of all, the limitation is not unambiguously defined because the comparison involves two varying factors....Secondly, neither the specification nor the art define the term 'a pharmacological effect' unambiguously, rendering the claims indefinite." (Page 8 of Final Office Action mailed 26 July 2006). Firstly, persons of ordinary skill in the pharmaceutical sciences understand that two variables can be assessed concurrently and compared. Thus, it is not understood how the need to assess "two varying factors" makes this functional limitation indefinite. Secondly, especially in view of the various methods described in detail in the application as filed, Applicants respectfully submit that a person of ordinary skill would easily understand the meaning of the phrase "a pharmacological effect" and the claims are not indefinite.

Rejection Under 35 U.S.C. § 102(b)

Claims 33, 47, 54, 56-60 and 62 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Yoshinaga, *et al.* The Examiner asserts that "because Yoshinaga, et al. teach a method of inhibiting pancreatic exocrine and gastric acid output, which are necessarily linked to other properties of PYY or PYY agonists,...the intended uses and properties of the PYY agonist analog (PYY(3-36)) recited in the claims are inherent to the method taught by Yoshinaga et al." (Page 10 of Final Office Action mailed 26 July 2006). Applicant traverses this rejection for reasons of record as well as those discussed herein.

As stated on page 14 of Applicant's response dated 17 May 2006, Yoshinaga does not teach or suggest reducing food intake, nutrient availability, caloric efficiency or appetite, nor reducing

weight, weight gain or increasing weight loss of the claimed invention. Nor does Yoshinaga teach the claimed subject populations, i.e., human subjects, subjects in need, or subjects having a condition or disorder which can be treated by reducing caloric efficiency, nutrient availability, food intake, appetite, body weight or body weight gain, or increasing weight loss. Yoshinaga is completely silent with respect to any of these claim limitations. Furthermore, there is no evidence that the missing limitations are inherent to the method taught by Yoshinaga. Moreover, with Applicant's response dated 17 May 2006, Applicants submitted three references showing that reduction in gastric acid secretion upon treatment with a peptide hormone is not inherently linked to a reduction in food intake or nutrient availability. Thus, the Examiner cannot reasonably conclude that the properties of the PYY agonist of Yoshinaga are "necessarily linked" to the properties of the claimed PYY agonist analogs of the invention. Yoshinaga does not teach, expressly or inherently, each element recited in the claims, and the 102(b) rejection is improper.

CONCLUSION

If any additional fee associated with this communication is due, the Commissioner is hereby authorized to charge payment to Applicant's Deposit Account No. 010535. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

Respectfully submitted,

Dated: 29-Sep-06

By: _____
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